UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

BAYER HEALTHCARE, LLC,

Plaintiff-Counterclaim Defendant,

v.

Case No. 08-C-0953
(Consolidated With
Case No. 09-C-0108)

NORBROOK LABORATORIES, LTD.,
and NORBROOK, INC. USA,

Defendants-Counterclaimants.

DECISION AND ORDER

Plaintiff, Bayer Healthcare, LLC ("Bayer") filed this patent infringement action against Defendants Norbrook Laboratories, Ltd. and Norbrook, Inc. U.S.A. (collectively to as referred "Norbrook"). The action relates to United States Patent Number 5,756,506 (the "'506 patent") and arises out of Norbrook's filing of an Abbreviated New Animal Drug Application ("ANADA") with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell in the United States a generic version of the injectable animal drug product BAYTRIL® 100, prior to the expiration of the '506 patent.

Norbrook filed a motion for judgment on the pleadings, pursuant to Fed. R. Civ. P. 12(c), seeking dismissal of the Complaint for failure to state a claim and for lack of subject

matter jurisdiction. The motion is ready for resolution and is addressed in this Decision and Order.

Subject matter jurisdiction is a threshold issue that the Court normally resolves early and considers at all stages of litigation. *United Phosphorus, Ltd. v. Angus Chem. Co.*, 322 F.3d 942, 946 (7th Cir. 2003). However, Norbrook's contention that the Court lacks subject matter jurisdiction over this matter is primarily based on its assertion that Bayer has failed to state a claim under 35 U.S.C. § 271(e)(2).[1] (*See* Norbrook's Mem. Supp. Mot. J. Pleadings 2.) As such, contrary to the usual practice, the Court will resolve the subject matter jurisdiction issue after analyzing Norbrook's contention that Bayer has failed to state a claim under § 271(e)(2).

In opposition to Norbrook's motion for judgment on the pleadings, Bayer filed the Declaration of Jamie Simpson ("Simpson Decl.") proffering evidentiary material outside the pleadings. *See* Simpson Decl., Ex. C (Defs.' Resp. Pl.'s First Set Interrogs.); Ex. D (Portions of the Defs.' Rule 30(b)(6) William G. Zollers, Jr. April 10, 2009, Dep. ("Rule 30(b)(6) Zollers Dep."); Ex. E-G (E-mails from the FDA to Defs. dated Feb. 24, 2009, Nov. 25, 2008, & Dec. 15, 2006, respectively); Ex. H (Defs.' Internal E-mail dated July 2, 2008); and, Ex. I (E-mail from Norbrook to the FDA dated Sept. 18, 2008.)

With Norbrook's reply memorandum in support of its motion for judgment on the pleadings, Norbrook also filed evidentiary material outside the pleadings with the Declaration of Eric Lobenfeld ("Lobenfeld Decl."). *See* Lobenfeld Decl., Ex. A (FDA

[1]Norbrook also contends that, because it has not yet obtained FDA approval and no one knows if or when that might happen, no Article III "case or controversy" exists.

Citizen Pet. Resp., Docket No. FDA-2003-P-0321/CPI dated April 6, 2004); Ex. B (Bayer Citizen Pet. submitted to the FDA dated June 13, 2006); Ex. C (Portions of Rule 30(b)(6) Zollers Dep.); Ex. I (Defs.' Supplemental Resps. Pl.'s First Set Interrogs. Nos. 3 & 5 served April 9, 2009); and, Ex. J (Defs.' Resps. Pl.'s First Set Interrogs. served March 17, 2009).

The parties do not address the impact of submitting these documents with respect to a motion for judgment on the pleadings. However, Rule 12(d) provides "If, on a motion under Rule . . . 12(c), matters outside the pleadings are presented to and not excluded by the court, the motion must be treated as one for summary judgment under Rule 56. All parties must be given a reasonable opportunity to present all the material that is pertinent to the motion." Because the motion for judgment on the pleadings was filed early in the proceedings and the parties have only engaged in limited discovery, and the issues involved in this litigation are complex, the Court declines to convert the motion for judgment on the pleading to a motion for summary judgment and has excluded the evidentiary materials outside the pleadings that have been proffered by Bayer and Norbrook.

APPLICABLE STANDARD

A motion for judgment on the pleadings pursuant to Federal Rule of Civil Procedure 12(c) is subject to the same standard as a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). *N. Ind. Gun & Outdoor Shows, Inc. v. City of South Bend*, 163 F.3d 449, 452 (7th Cir. 1998).[2] A district court may grant judgment on the pleadings if

[2]When considering procedural issues that are not unique to the patent law which is exclusively assigned to the United States Court of Appeals for the Federal Circuit, the Court applies the regional circuit law. *See Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1380-81 (Fed. Cir. 2002).

the moving party establishes that no material issues of fact remain to be resolved and it is clearly entitled to judgment as a matter of law. *Flora v. Home Fed. Sav. & Loan Ass'n*, 685 F.2d 209, 211 (7th Cir. 1982) (citing *Friedman v. Washburn Co.*, 145 F.2d 715, 717 (7th Cir. 1944)). The pleadings include the complaint, the answer, and any written instruments attached as exhibits. Fed.R.Civ.P. 10(c); *N. Ind. Gun & Outdoor Shows, Inc.*, 163 F.3d at 452.

The Court must view all facts pled as true and construe all inferences drawn from those facts in favor of the non-moving party. *Thompson v. Ill. Dep't of Prof'l Reg.*, 300 F.3d 750, 753 (7th Cir. 2002) (citing *Beam v. IPCO Corp.*, 838 F.2d 242, 244 (7th Cir. 1988); *Pleva v. Norquist*, 195 F.3d 905, 911 (7th Cir. 1999)). Pursuant to Federal Rule of Civil Procedure 8(c), a pleading must contain a "short and plain statement of the claim showing that the pleader is entitled to relief."

While the pleading does not require "detailed factual allegations," the standard has been refined to require more than an accusation that the defendant caused a harm. *Ashcroft v. Iqbal*, ___U.S.___ , 129 S.Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007))[3]. The reviewing court must draw on its judicial experience to determine whether a complaint states a plausible claim for relief. *Iqbal*, 129 S.Ct. at 1950. Therefore, the Court in its review must determine whether Bayer "'nudged

[3]Norbrook filed a notice of supplemental authority and submitted *Iqbal*, as supplemental authority to support of their motion for judgment on the pleadings.

[its] claims . . . across the line from conceivable to plausible.'" *See Iqbal*, 129 S.Ct. at 1950 (quoting *Twombly*, 550 U.S. at 570).[4]

STATUTORY BACKGROUND

Bayer's suit against Norbrook is based on the Generic Animal Drug and Patent Term Restoration Act ("GADPTRA"), codified at 21 U.S.C. § 360b. The law was enacted to provide the same benefits and regulation to animal drug products that were provided to human drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 ("Hatch-Waxman Act"), codified at 21 U.S.C. §§ 355, 360cc; 35 U.S.C. §§ 156, 271.[5] Congress enacted the Hatch-Waxman Act in an effort to harmonize two competing policy interests: "(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market." *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). Prior to the enactment of the Hatch-Waxman Act, the FDA could approve new drug products pursuant only to the filing of a new drug application ("NDA").

The Hatch-Waxman Act and GADAPTRA provide generic manufacturers with a shortened application process, known as Abbreviated New Drug Applications ("ANDA")

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[4]While *Twombly* retired the generous "no set of facts" standard, there was disagreement as to whether *Twombly* applied to all pleadings. *Iqbal* demonstrates that the *Twombly* pleading requirement applies to all Rule 12(b)(6) motions, and in this Circuit, to Rule 12(c) motions. *See Iqbal*, 129 S.Ct. at 1953; *Smith v. Duffey*, ___ F.3d ___ , 2009 WL 2357872, *4 (7th Cir. 2009). In *Iqbal*, the Supreme Court reinforced the rule that a claim is plausible "when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* at 1949 (citing *Twombly*, 550 U.S. at 556).

[5]There is little relevant GADAPTRA case law. As a result, the parties have primarily relied on the case law regarding its heavily-litigated human drug counterpart, the Hatch-Waxman Act. The statutory framework of the two acts is extremely similar. *Compare* 21 U.S.C. § 360b and 21 U.S.C. § 355. Therefore, the Court will also primarily rely on the Hatch-Waxman Act case law.

and Abbreviated New Animal Drug Applications ("ANADA") respectively.[6] The applicant for an ANDA or ANADA is not required to repeat safety or efficacy tests; instead, the applicant may rely on tests and studies done by the original pioneering drug company and its New Drug Application ("NDA") or New Animal Drug Application ("NADA"). *See Eli Lilly and Co. v. Teva Pharm. USA, Inc.*, 557 F.3d 1346, 1348 (Fed. Cir. 2009); 21 U.S.C. §§ 355(j), 360b(b)(2). The FDA lists pioneering human drug patents in the Orange Book, *Eli Lilly*, 557 F.3d at 1348, and pioneering animal drug patents in the Green Book,[7] *see* 21 U.S.C. §§ 355(b)(1) & (c)(2), 360b(c)(3).

When a manufacturer seeks FDA approval to market a generic version of a pioneering drug, its ANDA or ANADA must include a "certification" that addresses its relationship to the pioneering drug listed in the Orange or Green Book. *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)(I-IV), 360b(n)(1)(H)(i-iv). There are four types of certifications, designated as Paragraph I through IV, that may accompany an ANDA or ANADA. They are as follows: (I) the patent holder has not filed any information with the FDA; (II) the patent has expired; (III) the patent will expire on a certain date; and, (IV) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted. *Id.* These certifications are commonly referred to as a Paragraph I, II, III and IV certification, respectively.

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[6]The Court has treated ANDAs and ANADAs synonymously. The Court has also referred to human drug New Drug Applications ("NDA") and the New Animal Drug Applications ("NADA") interchangeably.

[7]A drug manufacturer that is approved for an NDA is required to notify the FDA of all patents that relate to the drug claimed in the NDA. *See Andrx*, 276 F.3d at 1371. The FDA lists such patents in the *Approved Drug Products With Therapeutic Equivalence Evaluations*, known as the "Orange Book." *Id.* The animal drug counterpart of the Orange Book is the *FDA Approved Animal Drug Products*, known as the "Green Book." 21 U.S.C. § 360b(c)(3). In this Decision and Order, the Court has used "Orange Book" and "Green Book" interchangeably.

The type of certification that accompanies an ANDA or ANADA has a profound influence on the speed of FDA approval. An ANDA or ANADA that contains a Paragraph I or II certification is approved immediately. *See* 21 U.S.C. §§ 355(j)(5)(B)(i), 360b(c)(2)(D)(i). Applications that have a Paragraph III certification and state that the applicant does not plan to market the generic until the patent expires receive FDA approval upon the expiration of the patent. *See* 21 U.S.C. §§ 355(j)(5)(B)(ii), 360b(c)(2)(D)(ii).

The statutory framework of the Hatch-Waxman Act and GADAPTRA mandate that an artificial act of infringement occurs when an applicant submits an ANDA or ANADA with a Paragraph IV certification. *See Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990); 35 U.S.C. § 271(e)(2). A generic manufacturer that submits a Paragraph IV certification is obligated to notify the pioneering drug manufacturer and provide a statement why the patent is invalid or why the generic drug will not infringe on the patent. *See* 21 U.S.C. §§ 355(j)(2)(B)(i)-(ii), 360b(n)(2)(A)-(B). The pioneering drug manufacturer then has 45 days to file a lawsuit under 35 U.S.C. § 271(e)(2). *See* 21 U.S.C. §§ 355(j)(5)(B)(iii), 360b(c)(2)(D)(iii). If the patentee does not sue, the ANDA or ANADA will be approved. *Id*. If the pioneering drug manufacturer does file a lawsuit, the FDA may not approve the ANDA or the ANADA until expiration of the patent, resolution of the lawsuit, or 30-months after the patentee's receipt of the notice, which ever is earlier. *Id*.

If the patent holder prevails in the lawsuit, the Court orders that the approval date of the generic's ANDA or ANADA shall not be earlier than the expiration of the patent of the pioneer drug. *See* 21 U.S.C. §§ 355(j)(5)(B)(iii)(II), 360b(c)(2)(D)(iii)(II); 35 U.S.C.

§ 271(e)(4)(A). If the district court decides that the patented drug is invalid or will not be infringed by the generic, the district court will lift the 30-month stay, and the FDA is permitted to approve the ANDA or ANADA. *See* 21 U.S.C. §§ 355(j)(5)(B)(iii)(I), 360b(c)(2)(D)(iii)(I).

Despite the likelihood of a lawsuit and 30-month stay, a generic manufacturer benefits from being the first to file an ANADA with a Paragraph IV certification. As an incentive for generic manufacturers to challenge a patented drug, the Hatch-Waxman Act and GADAPTRA provide a 180-day exclusivity period to the generic manufacturer who files the first Paragraph IV certification. *See* 21 U.S.C. §§ 355(j)(5)(B)(iv), 360b(c)(2)(D)(iv). When an ANADA with a Paragraph IV certification obtains approval, the FDA is forbidden from approving any other ANADAs based on the patentee's NADA for 180 days. *See* 21 U.S.C. §§ 355(j)(5)(B)(iv); 360b(c)(2)(iv).

In addition to the four "Paragraph" certifications, there is a method of use certification that may accompany an ANDA or ANADA. 21 U.S.C. §§ 355(j)(2)(A)(viii), 360b(n)(1)(I). A Section viii statement or Section I statement[8] is used when the generic applicant "seeks to market the drug for a use other than the one encompassed by the patent." *Purepac Pharm. Co. v. Thompson*, 354 F.3d 877, 880 (D.C. Cir. 2004) (citing 21 U.S.C. § 355j(2)(A)(viii)). Unlike a Paragraph IV certification, an ANDA with a Section viii statement does not require notification to the pioneer patentee of the filing and does not risk a 30-month stay. *Purepac*, 354 F.3d at 880. However, without risking a 30-month stay and

[8]A Section viii statement is the human drug certification that accompanies an ANDA. A Section I statement is the animal drug counterpart that accompanies an ANADA. The Court has used the terms interchangeably.

litigation, the generic manufacturer is not rewarded with 180-day market exclusivity. *Id.* (citing *Purepac Pharm. Co. v. Thompson*, 238 F. Supp. 2d 191, 195 (D.D.C. 2002)).

FACTUAL BACKGROUND

Bayer sells the injectable animal drug product, BAYTRIL® 100, that treats bovine respiratory disease. (Compl. ¶ 2.) Bayer submitted, and the FDA approved, a NADA for BAYTRIL® 100. (*Id.*) BAYTRIL® 100 is covered by one or more claims of the '506 patent"), entitled "Single High Dose Fluoroquinolone Treatment." (Compl. ¶¶ 17, 20.) Bayer owns the '506 patent. (*Id.* at ¶ 19.) Bayer's BAYTRIL® 100 is listed in the Green Book. (Compl. ¶ 20).

Norbrook filed ANADA No. 011-557 with the FDA seeking approval for a generic version of the injectable, animal product BAYTRIL® 100. (*Id.* at ¶¶ 1, 21.) Norbrook submitted its ANADA with a Paragraph IV certification. (*Id.* at ¶ 21.)

As required by statute, Norbrook notified Bayer by letter received by Bayer on September 29, 2008, (the "Notice letter") that it had submitted an ANADA, No. 011-557, for approval of a generic animal drug product which contains enrofloxacin[9] to treat cattle with bovine respiratory disease. (*Id.*) The Notice letter also stated that Norbrook had submitted to the FDA a "Paragraph IV certification" with respect to the '506 patent. (*Id.*) Upon information and belief, the purpose of the ANADA and the Paragraph IV certification was to obtain approval by the FDCA to engage in the commercial manufacture, use, offer for sale, sale and/or importation into the United States of an animal drug product which contains

[9]Enrofloxacin is an example of a fluoroquinolone and is preferred in the '506 patent. ('506 patent, 1:41-46.)

enrofloxacin to treat cattle with bovine respiratory disease prior to the expiration of the '506 patent. (*Id*.) Norbrook admits that it filed an ANADA with the FDA seeking approval to manufacture and sell in the United States its NORFLOXIN 100 (enrofloxacin injection, 100 mg/ml). (Answer & Countercl. ¶ 1.)

Bayer commenced this lawsuit on November 7, 2008, by filing a one-count Complaint, with the '506 patent attached. Bayer's Complaint states that Norbrook's filing of its ANADA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation into the United States of Norbrook's ANADA product prior to expiration of the '506 patent is an act of infringement on that patent in violation of 35 U.S.C. § 271(e)(2). (Compl. ¶ 24.) Bayer's Complaint states that, upon information and belief, Norbrook's ANADA product as described in Norbrook's proposed labeling will "encourage, suggest, teach, and/or induce the product's use in a single, high dose to treat cattle with bovine respiratory disease" and that Norbrook's ANADA product and its proposed labeling are not suitable for noninfringing use. (Compl. ¶¶ 27, 30.) Bayer's Complaint further states that Norbrook's actions constitute or will constitute active inducement of infringement under 35 U.S.C. § 271(b), and contribution to infringement by others under 35 U.S.C. § 271(c). (*Id.* at ¶ 31.)

On November 19, 2008, Norbrook filed its Answer and Counterclaims. In its Answer, Norbrook denied Bayer's allegations of direct, induced, and contribution to infringement. (Answer & Countercl. ¶ 31.) Additionally, Norbrook counterclaimed that the '506 patent is invalid, and sought declaratory judgment of non-infringement of the '506

patent and of no inducement to infringe the '506 patent. (*Id.* at ¶¶ 48-53.) Norbrook stated that it "submitted" ANADA No. 200-495[10] to the FDA under 21 U.S.C. § 360b(n), seeking approval for the commercial manufacture, use, sale, offer for sale, and importation into the United States of Norbrook's enrofloxacin injection, 100 mg/ml. (*Id.* at ¶ 45). Norbrook states that ANADA 200-495 contains a statement that in Norbrook's opinion and to the best of its knowledge, the '506 patent is invalid, unenforceable, and/or not infringed by Norbrook's ANADA product. (*Id.* at ¶ 46.)

On December 10, 2008, Norbrook filed an Amended Answer and Counterclaims. Norbrook stated that on December 1, 2008, Norbrook submitted an amendment to the FDA stating that it amended its ANADA with the FDA by withdrawing its Paragraph IV certification and substituting a Section I patent certification. (Am. Answer & Countercl. ¶ 21.) Norbrook also provided Bayer with a copy of its December 1, 2008, submission to the FDA. (*Id.*)

On February 2, 2009, Norbrook filed a Second Amended Answer and Counterclaims. Norbrook's Second Amended Answer also states that on December 1, 2008, Norbrook submitted an amendment to the FDA stating that it amended its ANADA with the FDA by withdrawing its Paragraph IV certification and substituting a Section I patent certification. (Second Am. Answer & Countercl. ¶ 21.) The second amended answer also alleges that the '506 patent is unenforceable because the patentees engaged in inequitable conduct before the United States Patent and Trademark Office ("PTO") (Second Am.

[10]The Court notes that Bayer and Norbrook have cited two different ANADA numbers.

Answer and Countercl. to Pl.'s Compl. ¶ ¶ 38, 62.) The Second Amended Answer adds details regarding Norbrook's counterclaim that the'506 patent is invalid.

Bayer's Answer to Norbrook's Second Amended Counterclaims admits that on December 1, 2008, counsel for Norbrook sent counsel for Bayer a document that purports to be an amendment to its ANADA. (Bayer's Answer to Second Am. Countercl. ¶¶ 9-10). The amendment purported to withdraw Norbrook's Paragraph IV certification and to submit a Section I certification to the '506 patent. (*Id*.) Bayer denies that Norbrook has withdrawn its Paragraph IV certification and substituted a Section I certification. (*Id*.)

CAUSE OF ACTION FOR INFRINGEMENT UNDER 35 U.S.C. § 271(e)(2)

Norbrook's Submission of an ANADA

Section 271(e)(2)(B) of Title 35 of the United States Code provides:

> It shall be an act of infringement to submit –
>
> (B) an application under section 512 of such Act . . . for a drug or veterinary biological product . . . which is claimed in a patent or the use of which is claimed in a patent,

if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent. 35 U.S.C. § 271(e)(2)(B).

In seeking judgment on the pleadings, Norbrook maintains that the amendment that it submitted to the FDA removes any liability under 35 U.S.C. § 271(e)(2). (Defs.' Mem.

Supp. Mot. J. Pleadings 7-8.) Norbrook also argues that, without a claim for direct infringement under § 271(e)(2), Bayer cannot maintain claims under § 271(b) and § 271(c). (*Id*. at 8.)

Norbrook concedes that the act of submitting an ANADA application with a Paragraph IV certification creates an artificial act of infringement under § 271(e)(2). (Defs.' Mem. Supp. Mot. J. Pleadings 9-10.) However, Norbrook argues that Bayer's infringement claim based on § 271(e)(2) fails to state a cause of action because Norbrook's ANADA no longer contains a Paragraph IV certification. (*Id*. at 13.) Thus, Norbrook states that the case law Bayer cites in support of its Paragraph IV infringement action do not support its position and support the unremarkable position that parties do not often dispute patent certifications or whether or not a Paragraph IV certification was "submitted." (Defs.' Reply Mem. Supp. Mot. J. Pleadings 10 n.5.)

Bayer's Complaint states that Norbrook infringed its '506 patent when Norbrook submitted an ANADA application with a Paragraph IV certification to the FDA. (Compl. ¶ 24.) In interpreting 35 U.S.C. § 271(e)(2)(B), Bayer maintains that Norbrook's infringement is based on the "submitted" application and that the act of filing an ANADA application with a Paragraph IV certification, itself, constitutes infringement. (Pl.'s Opp'n Norbrook's Mot. J. Pleadings 11.) Thus, Bayer maintains that, based on Norbrook's initial filing of a Paragraph IV certification, it has stated a claim under § 271(e)(2), regardless of what the application may later contain. (*Id*. at 11-12.)

In this case, the parties dispute the validity of Norbrook's purported withdrawal of its Paragraph IV certification and whether it was appropriate for Norbrook to file a Section I statement. Viewing the facts and construing all inferences from those facts in favor of Bayer, this Court cannot find that Norbrook has established that the FDA will approve the amendment and, therefore, conclude that the alleged infringing use is different. Thus, at this juncture of the proceedings, Norbrook has failed to establish, as a matter of law, that Bayer has failed to state a cause of action under § 271(e)(2)(B).

Moreover, even accepting that the December 1, 2008, amendment is effective, Norbrook has not established that to state a cause of action under § 271(e)(2) an ANADA must "contain" a Paragraph IV certification. In so contending, Norbrook relies on *Eisai Co. v. Mutual Pharmaceutical Co., Inc.*, No. 06-3613 (HAA), 2007 WL 4556958 (D.N.J. Dec. 20, 2007), and quotes the following statement: "the ANDA [or ANADA] must contain a Paragraph IV certification against a patent listed in the Orange [Green] Book," 2007 WL 4556958, at *12.

The quoted statement must be considered in context of the unusual circumstances of that case. In *Eisai*, the patent holder – Eisai – did not provide the correct patent information for a drug product that was necessary for the FDA's publication of the patent information in the Orange Book. *Id.* at *4. The FDA asked Eisai to resubmit the correct patent information. *Id.* However, Eisai failed to file the correct patent information with the FDA. *Id.* Thereafter, the generic manufacturer submitted an ANDA application that

had no certification regarding a specific patent.[11] *Id.* at *5. Subsequently, Eisai provided the FDA with the proper information causing the FDA to list that patent in the Orange Book. *Id.* at *13. However, the listing "came well after" the generic manufacturer filed its ANDA application. *Id.* at *13.

Under those circumstances, the *Eisai* court held that it would not require the ANDA applicant file a Paragraph IV certification as to that patent. *Id.* *14. The *Eisai* court declined to hold the generic manufacturer responsible for the errors committed by the patent holder. *Id.* at *13. In so holding, the court acknowledged the unusual situation and stated that if the patent had been properly listed in the Orange Book, an applicant seeking approval for a generic version of the drug would have been required to make a Paragraph IV certification. *Id.* at *13-14.

Norbrook construes *Eisai* as indicating that the Court should not hold Norbrook responsible for its own certification "mistake." However, *Eisai* is distinguishable because that ANDA application was filed without any type of certification for the relevant patent *and* the patent was absent from the Orange Book. *Id.* at *12-13. In this case, Bayer did not make a "mistake." Instead, Norbrook maintains that its Paragraph IV certification was a mistake.

Furthermore, the case law proffered by Bayer indicates that, even if Norbrook withdrew its Paragraph IV certification, Bayer may still maintain a cause of action under 35 U.S.C. § 271(e)(2)(B). *See Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1344 (Fed. Cir.

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[11] In *Eisai*, the ANDA applicant did not file a Paragraph IV certification or any other certification against the allegedly infringed patent. *Eisai Co.*, 2007 WL 4556958 at *5. However, the ANDA applicant had filed a Paragraph IV certification against four patents, even though at the time none of the patents were listed in the Orange Book. *Id.*

2004); *Teva Pharms. USA, Inc. v. Abbott Labs.*, 301 F. Supp. 2d 819, 829 (N.D. Ill. 2004). In *Glaxo Group Ltd.*, the Federal Circuit held that there can be an act of infringement under § 271(e)(2) even without a Paragraph IV certification. *See* 376 F.3d at 1351.

The issue arose in *Glaxo* and *Teva*, because the patents-in-suit had been approved under 21 U.S.C. § 357, a provision of the Federal Food, Drug, and Cosmetic Act ("FDCA") relating to antibiotics.[12] *See Glaxo*, 376 F.3d at 1344; *Teva*, 301 F. Supp. 2d at 828. When the Hatch-Waxman Act was passed, the FDCA had a separate section prescribing the regulatory process for approval to market antibiotic drugs, § 357. *Teva*, 301 F. Supp. 2d at 828. Thus, § 271(e)(2), which created the artificial act of infringement for seeking the approval of an ANDA under § 505(j) to obtain approval to make, use, or sell the generic drug prior to the expiration of the patent on the pioneer drug, did not apply to antibiotics, because manufacturers seeking regulatory approval to market generic versions of patented antibiotics did not seek approval under § 505(j). *Id.* However, § 271(e)(1), exempting from infringement the manufacture, use or sale of a drug for the purposes of developing and submitting information under a "federal law which regulates the manufacture, use, and sale of drugs," did apply to antibiotics. *Id.*

In 1997, the Modernization Act repealed 21 U.S.C. § 357, the old regulatory process for the approval of antibiotic drugs. *Id.* As a result, generic manufacturers of antibiotics must now apply for ANDAs under § 505(j). *Id.* However, the Modernization Act

[12]Section 357 was repealed, when Congress passed the Food and Drug Administration Modernization Act of 1997(the "Modernization Act"), Pub. L. No. 105-115, 111 Stat 2296 (1997). *See Teva*, 301 F. Supp. 2d at 828.

exempts antibiotic drug manufacturers who had filed previously under § 357 ("old antibiotics") from Orange Book listing and also exempts ANDA applicants for generic versions of old antibiotics from the certification requirements under § 355(j)(2)(A)(vii). *Id*. (citing *Glaxo Group Ltd. v. Apotex, Inc.*, 272 F. Supp. 2d 772, 777 (N.D. Ill. 2003); 21 U.S.C.A. § 355 Note (d)(2)("stating that § 355(j)(2)(a)(vii) 'shall not apply to any application for marketing in which the drug that is the subject of the application contains an antibiotic drug and the antibiotic drug was the subject of any application for marketing received by the Secretary of Health and Human Services under section 507 of [the FDCA] (21 U.S.C. § 357) before the date of enactment of this Act.'"). Because the pioneer antibiotic drugs were approved under § 357, the relevant patents in *Glaxo* and *Teva* were not listed in the Orange Book. *Teva*, 301 F. Supp. 2d at 828; *Glaxo*, 272 F. Supp. 2d at 777.

In *Teva*, the patent holder argued that, because the generic manufacturer was not required to file a Paragraph IV certification, § 271(e)(2)(A) which created an "artificial act of infringement" for filing an ANDA did not apply to Teva's ANDA. *Teva*, 301 F. Supp. 2d at 828-29. The court disagreed, holding that the language of § 271(e)(2)(A) did not require the ANDA contain a certification to constitute an act of infringement. *Id*. at 829. The court held that § 271(e)(2)(A) "only requires that an application be filed under § 355(j)." *Id*.

Norbrook argues that the holdings of *Glaxo* and *Teva* are irrelevant because the NDA drugs were specifically exempt from being listed in the Orange Book and were filed under 21 U.S.C. § 357. (Defs.' Reply Mem. Supp. Mot. J. Pleadings 6.) Although the pioneering antibiotic drugs and patents in *Glaxo* and *Teva* were approved under 21 U.S.C.

§ 357, the courts' analysis and statutory interpretation were rooted in § 271(e)(2) and; therefore, this inconsistency is irrelevant.[13] Moreover, while the district court's opinion in *Teva* is not binding, the Court agrees with its analysis of the issue and will follow that approach in concluding that Norbrook's filing of an ANADA is, itself, an act of infringement under 35 U.S.C. § 271(e)(2)(A). *See id.* at 829-30.

Whether an ANADA submission contains a paragraph IV certification or any certification is not critical under § 271(e)(2)(A), as long as "the purpose of such submission is to obtain approval . . . to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent." Norbrook does not dispute that it filed an ANADA under § 355(j). (Second Am. Ans. & Countercl. ¶ 21). Norbrook only contends that because it submitted an amendment to the FDA attempting to convert the paragraph IV certification to a Section I certification, and because "once an amendment is submitted, the application will no longer be considered to contain a certification," the ANADA no longer contains a Paragraph IV certification. (Defs.' Reply Mem. Supp. J. Pleadings 13).

Norbrook's proposed amendment, whether valid or invalid, does not change the fact that the ANADA was filed and that an infringement of the '506 patent may have occurred under § 271(e)(2). Therefore, it would be improper to dismiss the action based on Norbrook's contention that its application no longer contains a Paragraph IV certification

[13] The Federal Circuit held that filing an ANDA without a Paragraph IV certification did not remove the purpose of § 271(e)(2); that is, creation of an artificial act of infringement that enables a court to resolve infringement disputes. *Glaxo*, 376 F.3d at 1344. In *Teva*, the court held that an artificial infringement action under § 271(e)(2) only requires an ANDA that seeks to engage in the manufacture, use, or sale of a drug in a patent. *Teva*, 301 F. Supp. 2d at 830.

because a Paragraph IV certification is not required to trigger an infringement action under § 271(e)(2). *See Teva*, 301 F. Supp. 2d at 828-29.

The Definition of "Use" in § 271(e)(2)

Norbrook also maintains that its ANADA seeks FDA approval for a method of use not covered by the '506 patent. Section 271(e)(2)(B), states that "[i]t shall be an act of infringement to submit . . . [an ANADA] . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the *use* of which is claimed in a patent." (Emphasis added.)

Bayer and Norbook vigorously debate the correct interpretation of "use." Norbrook argues that "use" only refers to the "use" claimed in the '506 patent. (Defs.' Mem. Supp. Mot. J. Pleadings 10.) Conversely, Bayer argues that the Federal Circuit has interpreted "use" to encompass the use or uses for which the FDA approved in Bayer's NADA and refers to the compound used to treat the disease. (Pl.'s Opp. Defs' Mot. J. Pleadings 20.) Stated somewhat differently, Norbrook contends that its ANADA seeks a different use, treating bovine respiratory disease at multiple-day low-doses; whereas, Bayer argues that Norbrook's ANADA seeks approval for the same use, using the same drug to treat the same disease. (*Id.*, Defs.' Mem. Supp. Mot. J. Pleadings 10.)

In contending that it is not seeking the same "use," Norbrook states that it amended its ANADA application from a Paragraph IV certification to a Section I statement. (Defs.' Reply Mem. Supp. Mot. J. Pleadings 5.) However, as previously stated, there is no

indication that the FDA will accept Norbrook's amended Section I statement. Furthermore, the case law that Norbrook cites in favor of its amendment suggests that a Section I statement may not be appropriate, and that "use" refers to the disease treated, not the dosage.

Norbrook cites *Purepac Pharmaceutical Co. v. Thompson,* 354 F.3d 877, 880 (D.C. Cir. 2004), arguing that, if it had filed a Section I statement, because it would not have been required to give Bayer notice, this lawsuit would not exist. (Defs.' Reply Mem. Supp. J. Pleadings 6-7 (citing *Purepac Pharm*., 354 F.3d at 880 ("[a]pplicants submitting section viii [Section I] statements have no obligation to provide notice, nor must they wait thirty months for FDA approval.").) However, Norbrook has not demonstrated that its ANADA, even as amended, correctly fits within the defined "use" of a Section I Statement. Norbrook does not adequately address the language in *Purepac* that, "[if] the ANDA applicant seeks approval to use the drug to treat any other condition, then a section viii [or Section I] statement would be appropriate." *Id.*

In contending that Norbrook's ANADA seeks the same use as the '506 patent, Bayer also relies on *Purepac Pharmaceutical Co.*, 354 F.3d at 880, maintaining that Purepac demonstrates that the same drug used to treat the same disease, albeit at different dosages, is still the same "use." *Purepac* states that there is a different "use" when "a brand-name manufacturer's patent covers a drug's use for treating depression, and the ANDA [or ANADA] applicant seeks approval to use the drug to treat *any other condition*." *Id.* (emphasis added). As applied to the instant situation, Bayer's '506 patent covers enrofloxacin for treating bovine respiratory disease, and Norbrook's ANADA seeks approval

to use enrofloxacin to treat bovine respiratory disease. Norbrook does not seek to use the drug, enrofloxacin, to treat any other condition; it seeks to use the same drug to treat the same condition.

Norbrook also contends that Bayer's action against it cannot continue because Norbrook's amended ANADA seeks approval for a "use" not claimed in the '506 patent, (Defs.' Mem. Supp. Mot. J. Pleadings 10 (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348 (Fed. Cir. 2003).) Norbrook argues that the factual similarities between *Warner-Lambert* and the instant action demonstrate that Bayer's § 271(e)(2) claim cannot succeed.

In *Warner-Lambert*, the plaintiff patent holder, Warner-Lambert, sued the defendant ANDA applicant, Apotex, for infringement under 35 U.S.C. § 271(e)(2). *Id.* at 1353. Warner-Lambert claimed that Apotex sought approval for the same "use" as the one covered by its patent; that is, the treatment of neurodegenerative diseases with the drug gabapentin. *Id.* However, Apotex sought approval for the use of gabapentin to treat epilepsy only, a use that was not covered under Warner-Lambert's patent. *Id.* at 1360. The court granted summary judgment in favor of the defendant ANDA applicant "[b]ecause Apotex is not submitting an application to sell a drug for treatment of neurodegenerative diseases," but instead sought approval for the treatment of epilepsy. *Id.* at 1362.

Norbrook argues that "just as in *Warner-Lambert*," it is entitled to a favorable ruling that it is not seeking approval of the same "use" as covered by Bayer's '506 patent. (Defs.' Mem. Supp. Mot. J. Pleadings 10.) The circumstances of the instant case and those of *Warner-Lambert* are not analogous. In *Warner-Lambert*, the generic ANDA applicant

sought FDA approval for the use of gabapetin to treat epilepsy, as opposed to the patented neurodegenerative diseases. *Id.* at 1360. The Federal Circuit concluded that the ANDA applicant in *Warner-Lambert* did not seek approval for "the use of which is claimed in a patent" because the use was for treatment of a different disease. *See Warner-Lambert,* 316 F.3d at 1362.

However, in this case, Norbrook is seeking FDA approval for the use of enrofloxacin to treat the same disease covered by Bayer's '506 patent. Norbrook improperly analogizes the distinction made in *Warner-Lambert* for the same drug treating different diseases – neurodegenerative diseases and epilepsy — to the same drug treating the same disease at different dosages, as proposed by Norbrook. At this juncture of the proceedings, Norbrook has not demonstrated that, as a matter of law, Bayer cannot establish an infringing "use" under § 271(e)(2).

Bayer's § 271(b) and § 271(c) Claims

Norbrook contends that Bayer's § 271(b) and § 271(c) claims should be dismissed because those claims cannot survive without direct infringement under § 271(e)(2). (Defs.' Mem. Supp. Mot. J. Pleadings 19) (citing *Novartis Pharm. Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1308 (Fed. Cir. 2004)). However, this Court has determined that Norbrook has not established that Bayer has failed to state a § 271(e)(2) claim.

Moreover, Bayer's Complaint alleges that Norbrook's ANADA and its proposed labeling will constitute active inducement of infringement and contribute to the infringement by others of the '506 patent under § 271(b) and § 271(c). (Compl. ¶¶ 23-33.)

Additionally, Bayer claims that the limited discovery this Court allowed demonstrates that Norbrook's intent is that an FDA approved multiple-day low-dose be used in a single-day high-dose fashion that will induce or contribute to the infringement of the '506 patent. (*See* Pl.'s Opp. Defs.' Mot. J. Pleadings 22.)

Bayer states that exhibits submitted by Norbrook in support of its motion for judgment on the pleadings regarding the difficulty in the administration of a multiple day low-dose demonstrate that an approved low-dose generic would be used in the same single high-dose regimen of the '506 patent. (Pl.'s Resp. Defs.' Notice Supplemental Authority 3 (citing Compl. ¶¶ 25-33 and Lobenfeld Decl., Ex. B (Bayer's Citizen Pet. Submitted to the FDA dated June 13, 2006)).) Norbrook counters that its purported knowledge that veterinarians might use its low-dose generic in an infringing manner cannot pass muster for induced or contributory infringement.[14] (Defs.' Reply Notice of Supplemental Authority 2 (citing *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003).)

In addressing the difficulty of administering a multiple day low-dose medication, Bayer is relying on information outside the pleadings that this Court has excluded from consideration. Additionally, *Warner-Lambert* was decided on summary judgment. 316 F.3d at 1364.

In deciding the motion for judgment on the pleadings, the Court is not determining whether Bayer will be able to prove its claims. Rather, its role is to assess

[14] "[F]or purposes of deciding whether or not summary judgment . . . the mere knowledge of possible infringement by others does not amount to inducement; specific intent and action to induce infringement must be proven." *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1364 (Fed. Cir. 2003) (citing *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 554 (Fed. Cir. 1990).

whether, taken in the light most favorable to Bayer, the facts and inferences from those facts state a plausible claim for relief. Bayer has satisfied that standard.

Takeda Pharmaceuticals Co. v. Sandoz, Inc., No. 07 Civ. 3844, 2007 WL 2936208 *3-4 (S.D.N.Y. Oct. 9, 2007), supports the conclusion that Bayer's claims of contributory and induced infringement should not be dismissed on the pleadings. In *Takeda Pharmaceuticals*, the patentee's complaint alleged that the generic ANDA would infringe or induce others to infringe upon its patents. *Id.* at *2. Specifically, the patentee alleged that the generic manufacturer was aware of widespread off-label use in combination with other drugs that would infringe upon its patented combination therapy. *Id.* Like Bayer, the patentee alleged that, "based on information and belief," the generic's proposed label would not restrict the use of the generic drug or instruct physicians not to prescribe it in an infringing fashion.[15] *Id.* at *4. The *Takeda Pharmaceuticals* court held that such allegations satisfied the Rule 8 pleading standard and withstood the motion to dismiss.[16] *Id.*

Norbrook attempts to distinguish *Takeda Pharmaceuticals* because the generic manufacturer submitted a Paragraph IV certification and a Section viii statement. (Defs.' Reply Mem. Supp. Mot. J. Pleadings 14.) (citing *Takeda Pharms. Co.*, 2007 WL 2936208, at *2). While filing both a Paragraph IV certification and a Section viii statement is

[15]Bayer may allege an infringing proposed label without evidence of one. In *Takeda Pharmaceuticals*, 2007 WL 2936208, at *5 n.4, in support of its motion to dismiss, the generic manufacturer attached a proposed label; however, because it was not available when the complaint was filed, the court did not consider the label. The absence of a proposed label did not defeat *Takeda Pharmaceuticals*'s § 271(b) claim. *Id.* at *5.

[16]Although outside this appellate circuit, the *Takeda Pharmaceuticals* court applied the Rule 12(b)(6) standard to the Rule 12(c) motion to dismiss. *See* 2007 WL 2936208, at *3.

improper,[17] the court's analysis of the pleading requirement did not mention that the generic manufacturer had submitted two types of certification to the FDA. *See id* at *4. The generic manufacturer's incorrect certification did not impact the *Takeda Pharmaceuticals* court's cogent analysis of the pleading requirement for induced infringement. Norbrook has not established that Bayer's § 271(b) and § 271(c) claims should be dismissed.

SUBJECT MATTER JURISDICTION AND BAYER'S DECLARATORY JUDGMENT CLAIMS

In seeking dismissal for lack of subject matter jurisdiction, Norbrook argues that because Bayer has not stated a § 271(e)(2) claim, this Court lacks subject matter jurisdiction over this action. (Defs.' Mem. Supp. Mot. J. Pleadings 14.) "Subject-matter jurisdiction cannot be forfeited or waived and should be considered when fairly in doubt." *Iqbal*, 129 S.Ct. at 1949. For the purpose of resolving a motion to dismiss, the allegations of the Complaint are taken as true. *Pasco Int'l (London) Ltd. v. Stenograph Corp.*, 637 F.2d 496, 499 n.2 (7th Cir. 1980). Where, however, the Complaint "is formally sufficient but the contention is that there is in fact no subject matter jurisdiction, the movant may use affidavits and other material to support the motion." *United Phosphorus*, 322 F.3d at 946. In that case, the Court "is free to weigh the evidence to determine whether jurisdiction has been established." *Id.* (citing *Capitol Leasing Co. v. FDIC*, 999 F.2d 188 (7th Cir. 1993)). In all events, the party asserting jurisdiction bears the burden of proving its existence. *Id.* at 946.

The Court is not presented with a typical subject matter jurisdiction challenge because Norbrook's subject matter jurisdiction challenge rests primarily on its assertion that

[17]See *Purepac Pharmaceuticals*, 354 F.3d at 882.

Bayer has failed to state a cause of action for infringement. The Court has determined that Norbrook has not established that Bayer has failed to state a § 271(e)(2) infringement claim. Although Norbrook contends that it only seeks approval for the multiple-day low-dose treatment, Norbrook has not established that it can accomplish its goal without a Paragraph IV certification. Therefore, Bayer has satisfied its burden of establishing that the Court has subject matter jurisdiction over this action pursuant to § 1338(a). *See Eli Lilly and Co.*, 496 U.S. at 668-69.

Norbrook also contends that the Court should dismiss Bayer's declaratory judgment claims. To some extent, the parties agree that *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), sets forth the applicable legal standard; specifically, "that the dispute be 'definite and concrete, touching the legal relations of parties having adverse legal interests'; and that it be 'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc.*, 549 U.S. at 127 (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240 (1937)). However, the parties disagree about whether there is a substantial controversy of an immediate nature to warrant jurisdiction. (*Compare* Defs.' Mem. Supp. Mot. J. Pleadings 21; Pl.'s Opp. Defs.' Mot. J. Pleadings 31.)

Relying on *MedImmune*, Bayer argues that there is a "definite and concrete" dispute; that is, Norbrook seeks to market its FDA approved ANADA in a way that will infringe Bayer's '506 patent. (Pl.'s Opp. Defs.' Mot. J. Pleadings 26.) Additionally, Bayer

argues that discovery and depositions demonstrate that FDA may approve the ANADA in the immediate future. *Id.*

Norbrook maintains that FDA approval is uncertain and Norbrook has no immediate launch plans for its generic NORFLOXIN 100. (Defs.' Reply Mem. Supp. Mot. J. Pleadings 14.) Also, Norbrook argues that, even if it obtained FDA approval, the approval would be for a multiple low-dose variant over which Bayer has no patent rights, which belies Bayer's argument that a case or controversy exists. *Id.* at 13.

Applying *MedImmune*, the Federal Circuit held that there was an Article III controversy created based on the patentee's listing of patents in the Orange Book, the generic manufacturer's submission of an ANDA with a Paragraph IV certification, and the patentee's commencement of an action against the applicant challenging the ANDA. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007). Norbrook contends that *Teva Pharmaceuticals* does not apply because the generic manufacturer "undisputedly submitted a Paragraph IV Certification with their ANDAs." (Defs.' Reply Mem. Supp. Mot. J. Pleadings 13.)

While the parties debate whether Norbrook's ANADA still contains a Paragraph IV certification, they do not dispute that in September 2008, Norbrook submitted an ANADA with a Paragraph IV certification. At this juncture, for the reasons previously stated, the Court concludes that Norbrook's purported withdrawal of its Paragraph IV certification is not dispositive of Bayer's declaratory judgment claim. The circumstances presented in this action are sufficiently analogous to those of *Teva Pharmaceuticals* and

establish the existence of an Article III "controversy." *See Teva Pharm. USA, Inc.*, 482 F.3d at 1340.

Norbrook also argues that *Eisai* should control (Defs.' Mem. Supp. Mot. J. Pleadings 21). However, in *Eisai*, 2007 WL 4556958 at *9, the court determined that there was no § 271(e)(2) claim. Therefore, the decision in *Eisai* to decline a declaratory judgment claim is distinguishable from the circumstances of this instant action.

Summary

The Court cannot anticipate the FDA's actions with respect to Norbrook's ANADA or whether Norbrook's application will be found to infringe the '506 patent. However, Norbrook has not satisfied its burden of establishing that Bayer's action is subject to dismissal. Norbrook has not established that the lack of certification in an ANADA submission is fatal under § 271(e)(2)(a) or that the submission itself is not sufficient for infringement. At this juncture, Norbrook has not established that its product would be a non-infringing use or that Bayer's § 271(b) and § 271(c) claims should be dismissed. Furthermore, this Court concludes that it has subject matter jurisdiction over this action and that Bayer's declaratory judgment claims should not be dismissed. Therefore, Norbrook's motion for judgment on the pleadings is denied.

NOW, THEREFORE, BASED ON THE FOREGOING, IT IS HEREBY ORDERED THAT:

The evidentiary materials outside the pleadings proffered by Bayer and Norbrook with the April 16, 2009, Simpson Declaration, and the May 6, 2009, Lobenfeld

Declaration, respectively, have been excluded from the Court's consideration of Norbrook's motion for judgment on the pleadings; and,

Norbrook's motion for judgment on the pleadings (Docket No. 35) is **DENIED**.

Dated at Milwaukee, Wisconsin this 23rd day of September, 2009.

BY THE COURT

s/ Rudolph T. Randa
Hon. Rudolph T. Randa
U.S. District Judge